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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,753	06/24/2003	Jeffrey A. Robl	HX0117A-CIP DIV 1	1055

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,753	ROBL ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-36, 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 17-36, 42 are pending. Claims 12, 14, 15, 41, 43-44 have been canceled according to the amendment filed on 4-15-2004. Claims 1-11, 13, 16, 37-40, 45 are canceled according to the amendment filed on 6-24-2003.

Claim Rejections - 35 USC § 112(2)

2. The 112 second paragraph rejection for claims 17-36, 42 is withdrawn in view of Applicant's remarks and the amendment.

Claim Rejections - 35 USC § 112(1)

3. The rejection for Claims 17-36, 42 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

Applicant maintains that that utilities and examples of each of the therapeutic agents which are to employed in combination with the HMG CoA reductase inhibitors have been described in the specification. There is nothing in the reference mentioned by the examiner that would suggest that the claimed combinations should not be employed.

On the contrary, drug-drug interactions, both antagonistic and synergistic, are well known in the pharmaceutical art. The side effects resulting from the interaction between HMG-CoA reductase inhibitors and other lipid-lowering agents, as well as the antagonistic/synergistic effects of HMG-CoA reductase with additional therapeutic agent(s) have been described (Moghadasian MH, Life Sciences. 1999, 65(13):1329-1337, especially pages 1333-1334).

Furthermore, the relationship between the inhibition of HMG-CoA reductase and these different diseases has not been fully established (Waldman A and Kritharides L, Drugs. 2003, 63(2): 139-152, especially page 146, 2.4 Conclusions, and page 149, 3.4 Conclusions). At present, there is no umbrella drug known to treat and/or prevent all these diseases. At the time of the invention, a composition comprising a HMG-CoA reductase inhibitor and anti-cancer agents, anti-Alzheimer's agents etc. has not been described.

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The instant claims are directed to the composition comprising the inventive compound and other pharmaceutically active agents against myriads of diseases of diverse origins, thereby reaches out to as yet unidentified anti-cancer agents, anti-Alzheimer's agents etc., a description of which are not found in the specification. Applicant's claims does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the interaction between HMG-CoA inhibitors and other therapeutic agents, and the absence of working examples.

While some experimentation is permitted and every claimed embodiment need not be shown to possess the asserted activity, there should be a showing commensurate in scope with the claims. As stated in *In re Cavallito* 127, USPQ 202, "where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds, there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful....an applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others". Furthermore, in the instant HMG-CoA reductase inhibitor art, where there is a high degree of unpredictability exists, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. *In re Vaeck*, 20 USPQ 2d 1438.

In view of the state of the art, the high degree of unpredictability of the art, the absence of specific working examples, and the scope of the claims does not commensurate with that of the objective enablement, it is concluded that insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to make and use the invention as claimed without undue experimentation.

Conclusion

4. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

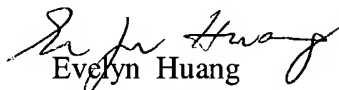
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625